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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 08/816,011 | 03/11/1997 | MARK H. PAUSCH | 34.421-C2 | 6532 |

22852 7590 09/25/2003

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EXAMINER

PAK, MICHAEL D

| ART UNIT | PAPER NUMBER |
|----------|--------------|
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1646

DATE MAILED: 09/25/2003

42

Please find below and/or attached an Office communication concerning this application or proceeding:

Office Action Summary

Application No.

08/816,011

Applicant(s)

PAUSCH, MARK H.

Examiner

Michael Pak

Art Unit

1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 March 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 22, 24, 27, 29, 30 and 33 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 22, 24, 27, 29, 30, 33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

Continued Prosecution Application

1. The request filed on 31 March 2003 (Paper No. 40) for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 08/816,011 is acceptable and a CPA has been established. An action on the CPA follows.
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Response to Arguments

2. Amendment filed 31 March 2003 (Paper No. 40) has been entered. Claims 22, 24, 27, 29-30, and 33 are pending.
3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
4. Applicant's arguments filed 31 March 2003 (Paper No. 40), have been fully considered but they are not found persuasive.

Claim Rejections - 35 USC § 101

5. Claims 22, 24, 27, 29-30, and 33 remains rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a substantial asserted utility or a well established utility.

Applicants argue that hypothetical Example 10 of the Guidelines regarding DNA ligase is analogous to the homology of the present invention to other potassium channels. However, unlike the DNA ligase, the potassium channels do not have a known utility.

The specification as filed does not disclose or provide evidence that points to a property of the claimed two pore potassium channel such that another non-asserted utility would be well established. The polypeptide lacks substantial utility because further research to identify or reasonably confirm a "real world" context of use is required. Thus, the asserted utility lacks substantial and specific utility because further research to identify or reasonably confirm a "real world" context of use is required. *Brenner V. Manson* 383 U.S. 519, 535-536, 148 USPQ 689, 696 (1966) stated that "Congress intended that no patents be granted on an chemical compound whose sole "utility" consists of its potential role as an object of use-testing ... a patent is not a hunting license." *Brenner* further states that "It is not a reward for the search , but compensation for its successful conclusion." Any utility of the nucleic acid encoding the protein or other specific asserted utility is directly dependent on the function of the protein. A circular assertion of utility is created where the utility of the protein is needed to break out the circular assertion of utility. The claimed polypeptides do not substantial utility because the skilled artisan would need to prepare, isolate, and analyze the protein in order to determine its functional nexus with human therapeutics. Therefore, the invention is not in readily available form. Instead, further experimentation of the protein itself would be required before it could be used. The disclosed use for the nucleic acid molecule of the claimed invention is generally applicable to any nucleic acid and therefore is not particular to the nucleic acid sequence claimed. The claims directed to vectors and host cells do not have utility because the nucleic acid without utility is needed to practice the inventions.

Art Unit: 1646

Claims 22, 24, 27, 29-30, and 33 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Claim Rejections - 35 USC § 112

6. Claims 24, 27, 29-30 and 33 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This a written description rejection.

Claim 24 encompass an isolated nucleic acid encoding variants and fragments of proteins because the claim is drawn to hybridization limitation without functional limitation. Claims 27, 29-30 and 33 are dependent on claim 24. The reason for the rejection was set forth in the previous office action. The newly amended claims now contain structural limitations which are generic and are not limited by functional limitation. However, the essential feature of the invention is the nucleic acid molecule which encodes a CORK two pore potassium channel of SEQ ID NO:36, and one of skilled in the art cannot envision the full genus of molecules of the claimed variant nucleic acid molecules.

Aplicants argue that applicants claim nucleic acids that encode functional proteins meeting particular described and claimed conditions. However, the claims do

Art Unit: 1646

not recite functional limitation which is specific for the CORK two pore potassium channel.

7. No claims are allowed.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Pak, whose telephone number is (703) 305-7038. The examiner can normally be reached on Monday through Friday from 8:30 AM to 2:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (703) 308-6564.

Official papers filed by fax should be directed to (703) 308-4242. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Michael D. Pak

Michael Pak

Primary Patent Examiner

Art Unit 1646

22 September 2003